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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,629	04/10/2001	W. Brent Lindquist	1079-3	7652

7590 03/11/2003

Jeffrey S. Steen
DILWORTH & BARRESE, LLP
333 Earle Ovington Boulevard
Uniondale, NY 11553

EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/829,629	LINDQUIST ET AL.
	Examiner	Art Unit
	Channing S. Mahatan	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 16 December 2002 is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449)	<u>1 Sheet</u>
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election with traverse of Group II (claims 18-42; drawn to a method for determining the effect of a substance on a neuron) in Paper No. 5, filed 06 September 2002, is acknowledged. Applicants' traversal is on the grounds that sufficient reasons has not been provided to show that a search burden exists and that in searching for algorithms useful in examining images to determine neuronal structures would necessarily find art relating to both Groups I and II is found persuasive.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-42.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

molecular biology is high, the results of experiments in genetic engineering are unpredictable.

While all of these factors are considered, sufficient amounts for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 1-42 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the disclosed processing module and analyzing module performing the specific steps described in Section A.1-A.5 (page 12, lines 6-7 of the Specification), does not reasonably provide enablement for the steps performed by processing module and analyzing module by any other means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The general outline of the processing module, as indicated by the specification, performs the steps of: 1) image deconvolution (iterative blurring deconvolution) and segmentation (page 12-13), dendritic backbone extraction (13-14); 3) spine detection (14-18); and 4) image registration and spine tracing (page 18). The general outline of the analyzing module, as indicated by the specification, performs the step of morphological characterization (pages 18-20, beginning on line 22). However, the specification fails to provide for other means by which to determine neuronal structure and/or determining the effect of a substance on a neuron. No other processing module(s) and analyzing module(s) are disclosed. None appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known practice to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 18 and all claims dependent therefrom from are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “a method for determining the effect of a substance on a neuron”, however the claim recites a final step of “comparing the at least one characteristic to a corresponding at least one characteristic of a control neuron”. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 14-17 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Spacek et al.

Spacek et al. performs a quantitative analysis of the smooth endoplasmic reticulum in dendritic spines and the parent dendrites to further understand the involvement of the smooth endoplasmic reticulum in the elevation and regulation of calcium at hippocampal synapses (instant claim 1; page 191, Column 1, lines 8-12 and Table 1). The authors establish a criteria for including and classifying dendritic spines according to shape categories; thin, mushroom, stubby, and branched (instant claims 14-17 and 36-49; pages 191-192, Columns 2-1, lines 24-31 and 1-5, respectively). Three-dimensional reconstructions and volumetric measurements were obtained for representative spines and the smooth endoplasmic reticulum or spine apparatus they contained (instant claims 3-9; page 196, Column 2, lines 23-25, Figure 8, and Table 2). Utilizing PC-based software outlines of the plasma membrane, postsynaptic densities, mitochondria, and smooth endoplasmic reticulum were traced from stored and “live” images (instant claim 2; page 192, Columns 1-2, lines 6-10 and 1-4). Additional, software was used to visualize the three-dimensional structure of the dendritic spines and their associated smooth endoplasmic reticulum, spine apparatuses, and dendritic segments (page 192, lines 7-11). Thus, Spacek et al. anticipates the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *March 7, 2003*
Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600
Art 1631